

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION)	MDL NO. 1203
<hr/>		
THIS DOCUMENT RELATES TO:)	
SHEILA BROWN, et al.)	
v.)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION)	2:16 MD 1203
)	

MEMORANDUM AND PRETRIAL ORDER NO.

Bartle, C.J.

August 22, 2007

Jamie L. Schlecht ("Ms. Schlecht" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").²

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See (continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. Part I of the Green Form is to be completed by the claimant or the claimant's representative. Part II is to be completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, Part III is to be completed by the claimant's attorney if he or she is represented.

In November 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Lorne E. Goldman, M.D., F.A.C.C. Based on an echocardiogram dated September 12, 2002, Dr. Goldman attested in Part II of her Green Form that she suffered from moderate mitral regurgitation and a reduced ejection fraction in the range of 50% to 60%. Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$604,222.

In the report of claimant's echocardiogram, Michael L. Hinnen, M.D., the reviewing cardiologist, stated that claimant

2(...continued)

Settlement Agreement §§ IV.B.2.b. and IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period, or who took the drugs for 60 days or less, or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

had "moderate mitral regurgitation through a valve with minimal leaflet thickening."³ Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22. Dr. Hinnen also estimated claimant's ejection fraction as 55%. An ejection fraction is considered reduced for purposes of a mitral valve claim if it is measured as less than or equal to 60%. See id.

§ IV.B.2.c.(2)(b).

In October 2003, the Trust forwarded the claim for review by Issam A. Mikati, M.D., one of its auditing cardiologists. In audit, Dr. Mikati concluded that there was no reasonable medical basis for Dr. Goldman's finding that claimant had moderate mitral regurgitation because her echocardiogram demonstrated only mild mitral regurgitation. In particular, Dr. Mikati observed that the "[mitral regurgitation] is clearly in mild range by Singh Criteria[.] [Mitral regurgitant] jet area is 2.3 cm²[.] [Left atrial] area is 19 cm² which is < 20%." Dr. Mikati, however, found that there was a reasonable medical basis for the attesting physician's finding of a reduced ejection fraction.⁴

3. Dr. Hinnen also noted that "[t]he possibility of fen-phen related mitral valve regurgitation must be considered."

4. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is
(continued...)

Based on Dr. Mikati's diagnosis of mild mitral regurgitation, the Trust issued a post-audit determination denying Ms. Schlecht's claim. Pursuant to the Rules for Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁵ In contest, claimant argued that the interpretations of Drs. Goldman and Hinnen provided a reasonable medical basis for her claim. In addition, claimant submitted a second echocardiogram report, dated December 5, 2003, which was performed by Michael A. Kwasman, M.D., who stated that claimant had "[m]oderate mitral regurgitation."⁶

Claimant also submitted a letter from John G. Peterson, M.D., dated January 7, 2004. Therein, Dr. Peterson acknowledged that he did not review claimant's September 12, 2002 echocardiogram but stated that her December 5, 2003

4(...continued)
diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust did not contest the attesting physician's finding of a reduced ejection fraction, which is one of the conditions needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

5. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Schlecht's claim.

6. Claimant did not submit a copy of her December 5, 2003 echocardiogram tape.

echocardiogram demonstrated "clear evidence of moderate mitral regurgitation based on the Singh Criteria." Claimant argued that the opinions of Drs. Kwasman and Peterson provided a reasonable medical basis for her claim.

The Trust then issued a final post-audit determination, again denying Ms. Schlecht's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7; PTO No. 2807 (Mar. 26, 2003), Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Schlecht's claim should be paid. On November 10, 2004, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 4135 (Nov. 10, 2004).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on June 1, 2005. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor⁷ to review claims after the Trust and

7. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In cases, such as here, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor's Report are now before the court for final determination. Id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there was no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must confirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there was a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Schlecht argues that: (1) Drs. Goldman and Hinnen determined that her September 12, 2002 echocardiogram demonstrated moderate mitral regurgitation; (2) the auditing cardiologist, Dr. Mikati, failed to explain the disparity between his findings and those of Drs. Goldman and Hinnen; and (3) the Trust did not consider the December 5, 2003

echocardiogram and the supplemental opinions of Drs. Kwasman and Peterson.⁸

In addition, claimant submitted: (1) a supplemental expert opinion, dated December 21, 2004, by Allan J. Stahl, M.D., F.A.C.C. stating that the September 12, 2002 echocardiogram demonstrated moderate mitral regurgitation "filling about 40% of the atrium;" (2) a supplemental expert opinion, dated December 20, 2004, by Dr. Peterson stating that the September 12, 2002 echocardiogram demonstrated moderate mitral regurgitation with a measurement of 27% in the two-chamber view and 42% in the apical four-chamber view; and (3) a declaration from Ms. Schlect dated December 22, 2004, stating that she was unrepresented prior to her show cause proceedings.

In response, the Trust argues that: (1) Dr. Mikati adequately explained his findings in audit; (2) the expert opinions of Dr. Stahl and Peterson do not establish a reasonable medical basis for the attesting physician's representation of moderate mitral regurgitation because Dr. Mikati found that claimant had mild mitral regurgitation with an RJA/LAA of 12.1%; and (3) the standard of review at audit is whether there is a reasonable medical basis for the attesting physician's

8. Claimant also asserts that Dr. Hinnen, who performed claimant's September 12, 2002 echocardiogram, participated in the Trust's Screening Program established under the Settlement Agreement. See Settlement Agreement § IV.A.1. As claimant does not explain how Dr. Hinnen's participation in the Screening Program establishes a reasonable medical basis for her claim, his participation in the program is irrelevant.

representation, "not whether one party can collect more opinions than the other."

The Technical Advisor, Dr. Vigilante, reviewed claimant's September 12, 2002 echocardiogram and concluded that there was reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation. Specifically, Dr. Vigilante found that:

A jet of mitral regurgitation was noted in the parasternal long axis view. Mitral regurgitation was obvious in both the apical two chamber and apical four chamber views. This mitral regurgitant jet was a central to mildly posterolaterally displaced jet. The mitral regurgitation was most impressive in the apical four chamber view. Representative frames of the RJA and LAA were measured in all evaluable cardiac cycles in the apical four chamber view. It should be noted that this mitral regurgitant jet approached the posterior wall of the left atrium in each of the cardiac cycles. The RJA/LAA was measured to be between 30%-35% in each of these cardiac cycles. It was obvious that the mitral regurgitation was moderate in severity. I am unable to explain how the Auditing Cardiologist found an RJA/LAA ratio of 12.1%.

After reviewing the entire Show Cause Record before us, we find that claimant has established a reasonable medical basis for her claim. Claimant's attesting physician reviewed claimant's echocardiogram and found moderate mitral regurgitation.⁹ Although the Trust contested the attesting

9. Although unnecessary for resolution of this claim, as noted above, claimant also submitted expert opinions of two additional cardiologists who similarly concluded that claimant had moderate mitral regurgitation.

physician's conclusion, Dr. Vigilante confirmed the attesting physician's findings.¹⁰ Specifically, Dr. Vigilante concluded that "there is a reasonable medical basis for the Attesting Physician's answer to Green Form Question C.3.a. That is, the echocardiogram of September 12, 2002 demonstrated moderate mitral regurgitation with the RJA/LAA of 20%-40%."

As stated above, moderate or greater mitral regurgitation is present where the RJA in any apical view is equal to or greater than 20% of the LAA. See Settlement Agreement § I.22. Here, Dr. Vigilante found that moderate mitral regurgitation was "obvious" in the apical four chamber view. Under these circumstances, claimant has met her burden in establishing a reasonable medical basis for her claim.¹¹

For the foregoing reasons, we conclude that claimant has met her burden in proving that there is a reasonable medical basis for her claim and is consequently entitled to Matrix A-1, Level II benefits. Therefore, we will reverse the Trust's denial of the claim submitted by Ms. Schlecht for Matrix Benefits.

10. Despite an opportunity to do so, the Trust did not submit any response to the Technical Advisor Report. See Audit Rule 34.

11. Accordingly, we need not address claimant's remaining arguments.

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/)	
FENFLURAMINE/DEXFENFLURAMINE))	MDL NO. 1203
PRODUCTS LIABILITY LITIGATION)	
)	
THIS DOCUMENT RELATES TO:)	
)	
SHEILA BROWN, et al.)	
)	CIVIL ACTION NO. 99-20593
v.)	
)	
AMERICAN HOME PRODUCTS)	2:16 MD 1203
CORPORATION)	
)	

PRETRIAL ORDER NO.

AND NOW, on this 22nd day of August, 2007, for the reasons set forth in the accompanying Memorandum, it is hereby ORDERED that the final post-audit determination of the AHP Settlement Trust is REVERSED and that claimant Jamie Schlect is entitled to Matrix A-1, Level II benefits. The Trust shall pay such benefits in accordance with the Settlement Agreement and Pretrial Order No. 2805 and shall reimburse claimant for any Technical Advisor costs incurred in the Show Cause process.

BY THE COURT:

/s/ Harvey Bartle III

C.J.